FEB 1 6 2001



K003932

# 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

# FOR

# BOSTON EO (enflufocon B) RGP Contact Lens for Orthokeratology

## 1. SUBMITTER INFORMATION:

Polymer Technology
Global Vision Care
1400 N. Goodman Street
P.O. Box 30450
Rochester, New York 14603-0450

## 2. CONTACT PERSON:

Nancy A. Abraham
Regulatory Affairs Specialist
Address: 1400 North Goodman Street
P.O. Box 30450
Rochester, New York 14603-0450
Telephone No.: (716) 338-8227
Fax No.: (716) 338-0702
E-mail Address: Nancy_A_Abraham@bausch.com

## 3. DEVICE IDENTIFICATION:

Classification Name: Rigid Gas Permeable (hydrophobic) Contact Lens

Proprietary Name: BOSTON EO (enflufocon B) Contact Lens for Orthokeratology

Common Name: Fluoro silicone acrylate rigid gas permeable contact lens material

## 4. PREDICATE DEVICE:

The *BOSTON EO (enflufocon B) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed BOSTON XO (hexafocon A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on August 28, 2000 in 510(k) Premarket Notification No. K001960.

## 5. DESCRIPTION OF THE DEVICE:

The *BOSTON EO (enflufocon B) RGP Contact Lens for Orthokeratology* is composed of aliphatic fluoroitaconate siloxanyl methacrylate copolymer.

The material is available in blue, ice blue, green, brown, or gray tint, The lenses may contain an ultraviolet light absorber, Uvinul D-49. The blue tinted lenses contain the color additive D&C Green No. 6; the green tinted lenses contain color additives D&C Green No. 6 and D&C Yellow No.10; the brown tinted lenses contain additives D&C Green No.6, D&C Yellow No.10 and D&C Red No.17, the gray tinted lenses contain color additives D&C Green No.6, D&C Yellow No. 10 and D&C Red No.17, and D&C Violet No. 2. All of those color additives are listed in the Code Of Federal Regulations.

The enflufocon B material has an oxygen permeability (Dk) of 82, a specific gravity of 1.23, and the lens visible light transmittance of at least 70%. The enflufocon B name has been adopted by the Unites States Adopted Names Council (USAN)

The *BOSTON EO (enflufocon B) RGP Contact Lens for Orthokeratology* is a rigid gas permeable contact lens in a reverse geometry design. The lens material, which is enflufocon B, is a fluoro silicone acrylate material.

## 6. INDICATIONS FOR USE:

The *BOSTON EO (enflufocon B) RGP Contact Lens for Orthokeratology* is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters for non-diseased eyes. The lens must be disinfected using a chemical disinfection system only.

Note: To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

## 7. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE:

The safety and efficacy of *BOSTON EO (enflufocon B) Contact Lens Material* was demonstrated in 510(k) Premarket Notification No. K980741, cleared on May 11, 1998. Also, the use of a rigid gas permeable contact lens in a daily wear orthokeratology program for temporary reduction of myopia of up to 3.00 diopters was approved in the BOSTON XO (hexafocon A) Rigid Gas Permeable Contact Lens for Orthokeratology 510(k) Premarket Notification No. K001960, cleared on August 28, 2000.

## 8. SUBSTANTIAL EQUIVALENCE

The *BOSTON EO (enflufocon B) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed BOSTON XO (hexafocon A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on August 28, 2000 in 510(k) Premarket Notification No. K001960.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 6 2001

Nancy Abraham
Regulatory Affairs Specialist
Polymer Technology Corporation
1400 N. Goodman Street
Rochester, NY 14603

Re: K003932
Trade Name: BOSTON EO (enflufocon B) Rigid Gas Permeable Contact Lens for Orthokeratology (Daily Wear Clear and Tinted)
Regulatory Class: II
Product Code: 86 HQD, MUW
Dated: December 19, 2000
Received: December 20, 2000

Dear Ms. Abraham:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device when worn overnight in an orthokeratology fitting and maintenance program have not been established.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System

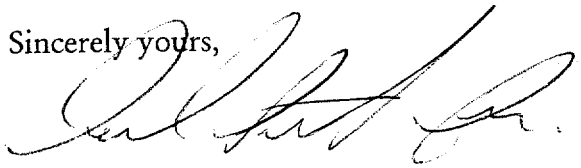
Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97.) Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

k003932

Polymer Technology
1400 North Goodman Street
P.O. Box 30450
Rochester, New York 14603-0450

## INDICATIONS FOR USE STATEMENT:

510 (k) number (if known)

Device Name: BOSTON EO (enflufocon B) RGP Contact Lens for Orthokeratology

Indications For Use:

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Note: To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

**Prescription Use** ✓
**(Per 21 CFR 801.109)**

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number k003932